National Organic Standards Board
Certification, Accreditation, and Compliance Subcommittee
Residue Testing for a Global Supply Chain: Regulation Review Discussion Document

Executive Summary

The Fall 2024 Discussion Document on Residue Testing for a Global Supply Chain highlighted several areas in the regulations that may need revision. These include:

1. **Exclusion from organic sale (§205.671):**
    a. Lack of clarity on whether the detection of direct prohibited material application (intentional, regardless of where or when) can or should be excluded from sale as organic per §205.671 Exclusion from sale
        i. Downstream notification of contamination when known
2. **Unavoidable residual environmental contamination (UREC) Definition (§205.2):**
    a. Revision to the definition of UREC
3. **Number and Cost of Sampling and Testing (§205.670):**
    a. Exploration regarding the cost and number of sample collection and testing (i.e., should certifiers continue to bear the expenses of residue sampling and testing in all scenarios, including follow-up tests)

Discussion

1. Exclusion from organic sale (§205.671)

The organic program has experienced exponential growth since the pesticide rule came into effect, and threats to integrity are ever-present. When the pesticide rule was being discussed, commenters stated that the regulation at §205.671 could be misinterpreted to allow products to be sold as organic when prohibited substances were applied if the tests showed levels of the prohibited substance less than 5% of EPA tolerance. Intentional or direct application of prohibited substances to a crop or product, regardless of whether the residue detected is below 5% of the EPA tolerance or FDA action level, should not be sold, labeled, or represented as organically produced. Clarity is needed to reconcile the regulatory text with the Organic Foods Production Act (OFPA).

Background/Regulatory References:

- Section 6511 of the Organic Foods Production Act (OFPA) states:

  (c)(2) *Removal of organic label.* If, as determined by the Secretary, the applicable governing State official, or the certifying agent, the investigation conducted under paragraph (1) indicates that the residue is—
  (A) the result of the intentional application of a prohibited substance or
  (B) present at levels greater than unavoidable residual environmental contamination as prescribed by the Secretary or the applicable governing State official in consultation with the appropriate environmental regulatory agencies; such agricultural product shall not be sold or labeled as organic under this title.

- 7 CFR Part 205 National Organic Program Regulations states:

§ 205.671 Exclusion from organic sale. When residue testing detects prohibited substances at levels greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced. The Administrator, the applicable State organic program's governing State official, or the certifying agent may investigate the certified operation to determine the cause of the prohibited substance.

- 2013 Periodic Reside Testing Final Rule (77 FR 67239) - Preamble Response to comments state:

  (3) *Exclusion from Organic Sale*. Commenters expressed that section 205.671(a) could be easily misinterpreted. They said that section 205.671(a) did not make clear that residue testing may not be used to qualify crops to be sold as organic if a direct application of prohibited materials occurred. Commenters suggested that section 205.671(a) include: "Any crop or product, to which prohibited materials have been directly applied, shall not be sold, labeled, or represented as organically produced."

  NOP Response: We do not believe this additional language is necessary. Residue testing cannot be used to qualify any agricultural crop or product to which a prohibited material has been purposefully/directly applied. The presence of any prohibited substance on an agricultural product to be sold as organic warrants an investigation as to why the detected prohibited substance is present on the agricultural product. It does not matter if the product has come into contact with a prohibited substance through drift or intentional application. Suppose the outcome of the investigation reveals that the presence of the detected prohibited substance is the result of an intentional application. In that case, the certified operation will be subject to suspension or revocation of its organic certification and/or a civil penalty of not more than $10,000 if he/she knowingly sells the product as organic. The use of prohibited substances is not allowed in the Act or this final rule. Residue testing does not qualify a crop or product as organic if a prohibited substance has been intentionally/directly applied. It is a tool for monitoring compliance with the regulations outlined in the Act and this part.

- EU Regulations Articles 28 and 29 of EU 2018/848

  Article 29 (2) “The product concerned shall not be marketed as organic if the official investigation concludes that an operator has used non-authorized products or substances, has not taken the appropriate precautionary measures to avoid the risk of contamination, or has not taken measures in response to relevant previous requests from the competent authorities, control authorities or control bodies.

  SEE REFERENCE: A Vade Mecum on Official Investigation in Organic Products

  (2024) – Good Implementation Practices for Articles 28 and 29 of Regulation (EU) 2018/848. It can be downloaded for free here.

Compliance Process Overview:

- In regard to prohibited substances, there are two compliance pathways a certifier can take:
  1. Exclusion from organic sale (§205.671)
  2. Noncompliance procedure for certified operations (§205.662)

Exclusion from organic sale currently only applies to products that contain pesticide residues greater than FDA action levels or 5% of EPA tolerances. This means that certifiers can immediately exclude contaminated products from the organic marketplace. Additionally, certifiers may also follow the procedures outlined in §205.662, depending on the determination of why the residue is present.

Certifiers must follow the applicable compliance procedures for all other prohibited substances (not pesticides). The immediate exclusion from organic sale under §205.671 does not apply. The product ultimately may be excluded from sale if the operation's organic certification is suspended or revoked.

Section Summary:
NOSB is reviewing the possibility of amending §205.671 of the regulations to clarify that an intentional application of a prohibited substance or excluded method removes the organic label (a.k.a. exclusion from sale as organic), regardless of whether a tolerance level is established.

Also, the NOSB is reviewing whether the NOP should instruct certifiers to require operations to inform downstream buyers of crops or products with exclusion-level contamination, which could lead to increased oversight and testing via organic fraud prevention plans. With SOE, supply chain traceability is one of the major deliverables. Also, we only "know what we know," so additional feedback to inform certified operations fraud prevention plans is essential for continuous improvement.

Public Comment Summary:
During the Fall 2024 meeting, the NOSB asked a series of questions about §205.671. The responses are summarized below and assisted in the formation of the discussion above:

In general, commenters favored achieving alignment for exclusion of sale, especially when an intentional application earlier in the season yields a "passing" result on a test based on EPA Tolerances or FDA Action Level. In addition, it clarifies the intentional application of other prohibited substances (outside of pesticides) and excluded methods.

- More flexibility: Provide certifiers with more flexibility to exclude products from the organic marketplace when residues of prohibited substances are detected in non-crop samples such as soil, water, or tissue. The exclusion mechanism should not be limited to pesticide residues, but should apply to any substance that jeopardizes organic integrity. Note: EU regulation 2018/848 can be benchmarked.

- Eliminating noncompliant materials from the supply chain: A commenter mentioned holding orders. At the same time, a product analysis or investigation would motivate proactive prevention and increase supply chain preparation for sampling. The regulatory authority to exclude or recall products voluntarily or mandatorily would bolster consumer confidence in organic supply.

Differentiation between certain types of materials: One commenter stated that a regulatory mechanism is needed to distinguish between materials that have an agricultural or food processing use in nonorganic crops and products and materials that may occur naturally, such as nicotine in peppers and arsenic in rice. They said this regulatory mechanism should be based on a closed list of prohibited

materials that wouldn't exclude products from the organic marketplace if a material is detected because it occurs naturally.

Willful violations: A certifier stakeholder mentioned that certifiers have other means of investigation and enforcement, such as 7 CFR 205.662(d) and NOP 4002 (Penalty Matrix), that could prevent a contaminated product from entering the organic supply chain. However, addressing NOP 2613 to cover residue detections other than pesticides would make it easier for certifiers to enforce. If enough evidence is collected to show a willful violation was committed, a certifier can move forward with the proposed revocation of the entire operation.

2. Unavoidable residual environmental contamination (UREC) Definition (§205.2)

Under OFPA and the NOP regulations, organic certification is a process-based standard. However, consumers expect organic products to be free of any contamination with prohibited substances. This expectation is becoming increasingly challenging to meet as technology advances, allowing substances to be detected in trace amounts. Often, the contamination is outside the organic operation's control (e.g., contamination from adjoining land, atmospheric drift, etc.). Certifiers must use current EPA tolerances to determine if the organic product is eligible to be sold as organic. Due to this increased contamination reality, it is not uncommon for residues to be present at low levels, but there is no EPA tolerance established for that crop. Therefore, certifiers must use the .01 ppm level as the benchmark to determine the eligibility of organic products. In an ideal world, all substances would have a value for all crops or crop groups, so certifiers wouldn't need to default to .01 ppm. However, this is impossible.

In place of that ideal world, CACS is exploring how to bring these pieces more into alignment: the current reality of farming in today's landscape (which does, unfortunately, contain some level of contaminants) and certification being a process-based standard with consumer expectations of zero prohibited substances being in organic products even at trace amounts, for certifiers to respond to positive test results in a pragmatic yet compliant manner.

Section Summary:

Current definition at §205.2:

> *Unavoidable residual environmental contamination (UREC).* Background levels of naturally occurring or synthetic chemicals present in the soil or in organically produced agricultural products below established tolerances.
>
> Based on stakeholder comments, NOSB proposes the following revision to the definition of UREC:
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> 1. *Unavoidable Residual Environmental Contamination (UREC).* Background levels of ~~naturally occurring or synthetic chemicals~~ prohibited substances and excluded methods that are ~~present in the soil or present in organically produced agricultural products that are below established tolerances~~ not caused by actions taken by organic farmers and ranchers and are, hence, typically beyond the control of certified organic operations.

NOTE: Additionally, NOP 2613 would require updates based on the ultimate approach decided for UREC. When regulations are updated, we understand that subsequent guidance document(s) updates occur.

Public Comment Summary:

In addition to updating the UREC definition, the NOSB received comments about UREC during the Fall 2024 meeting. The responses are summarized below and assisted in the formation of the discussion above:

Unfair punishment: A commenter indicated that we should be cautious about penalizing operations when there is no EPA tolerance, which defaults to 0.01 ppm even when the contamination is UREC. In that case, the product should be allowed to be sold as organic.

Rethinking the link to EPA tolerances concerning UREC: A commenter suggested that basing UREC levels of pesticides on a percentage of EPA-set tolerances is arbitrary and doesn't link to human health impact. They suggested an alternative approach, such as setting UREC levels concerning chronic Reference Doses (cRfDs) and defining inadvertent residues (e.g., 1/10th of a pesticide found in conventional samples).

Additional review is an investigative burden: An organic stakeholder mentioned that organic farmers often face the burden of investigations when pesticide residues are detected, even when they are trace amounts likely linked to environmental factors beyond their control - UREC. The extensive documentation and interviews required following such detections can detract from the farmers' primary operations. Streamlining investigative procedures, particularly in UREC cases, would help alleviate this issue. By adopting more efficient protocols, certifiers can ensure that farmers are not unduly burdened with investigations that are unlikely to yield substantial improvements in compliance.

3. Number and Cost of Sampling and Testing (§205.670)

205.670(c) states, "A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." Samples may include collecting and testing soil, water, waste, seeds, plant tissue, plant, animal, and processed product samples. **Such tests must be conducted by the certifying agent at the certifying agent's own expense**" (bolded for emphasis).

205.670(d) states: **A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number.** A certifying agent that certifies fewer than thirty operations annually must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.

Section Summary:

Due to the regulatory references above, certifiers feel constrained from performing testing above the required 5%. However, if certifiers could pass the costs along to certified operations for increased oversight activities deemed necessary (e.g., complaint, investigation, high-risk operation), certifiers would likely increase the number of samples collected.

It is our understanding the certifiers are experiencing this inconsistently. Some pass along the cost to operations for complaints and investigations and do not count this towards their 5%, which appears compliant (haven't received noncompliance). In contrast, others have received noncompliances for passing the costs along in the same situations.

Public Comment Summary:

The NOSB received several comments regarding costs. Conducting 5% residue testing is a very high-dollar line item on a certifier's profit and loss statement (P&L). There is an incredible amount of variability in this cost value, especially when business decisions are made to manage to a budgetary number versus conducting the needed tests on a risk basis, which could require more travel, subsequent visits, more complex sample collection, etc. One certifier stakeholder mentioned that due to managing costs, they were not in favor of conducting multiple visits for sampling.

Risk: One commenter mentioned that a uniform 5% pesticide testing rate does not adequately address the varying levels of risk across different operations. It can disproportionately burden low-risk organic farms with unnecessary testing while under-scrutinizing operations at higher risk for contamination. This creates inefficiencies and places undue financial and operational strain on organic farmers, particularly small and medium-sized operations. Another commenter mentioned that fraud has been documented in imported and domestic corn, but evidence for other categories was limited. If changes in the residue testing program happen, it is critical that the response targets areas of the documented risk surveillance testing program, which would also be helpful to evaluate. A consultant for a processor mentioned that since the current mandate is that 5% of all operations have a single test performed under the regulation, it is entirely conceivable that not all pesticide residues would be caught, even at the producer level. Therefore, pesticide residue testing should be standardized and required of all producers, regardless of crop.

Re-allocating Costs: Several public commenters believed in the opportunity to explore spreading out the costs throughout the industry. One certifier mentioned that we could reasonably test 10% of operations annually without considering costs.

Other factors outside of costs: Crop timing can limit the collection of a limiting sample in addition to human capital resources.

Discussion Document Conclusion:
The regulations governing residue testing have remained largely unchanged since 2013, following notable revisions, while certain provisions, such as UREC, have been in place for even longer. However, the organic industry has evolved dramatically since then. It is both wise and essential—rooted in the very principles of organic production and certification—to consistently assess and enhance our practices to ensure we thrive in a dynamic marketplace. Now is the time to revisit and refine these regulations, celebrating the effective elements and courageously reimagining those that no longer serve our vibrant industry.

Questions:

1. **Exclusion from Sale:**
    a. Outside of EPA tolerances/FDA action levels, are certifier and inspector tools sufficient to determine willful violations of prohibited substances in categories other than pesticides, i.e., solvents, excluded methods, and fertilizer?
    b. Is it necessary to expand 205.671 to include intentional applications, or are other parts of the regulations allowing certifiers to exclude products from sale that were not produced under the regulations?
    c. Is there value in informing downstream supply chain recipients when known non-compliant products have been discovered and released into the "chain of commerce?"
        i. What are the unintended consequences?

d. There have been cases where questionable products have been received. Still, testing is avoided to confirm compliance due to the significant financial risk of knowing the product could be non-compliant (e.g., an imported product received that is already paid for). What are the solutions here?

2. UREC:

a. Do you agree with the proposed revision to the definition of UREC?
b. Do you have an alternative definition to propose?
c. Should guidance be revised to state that noncompliances should not be issued if the residue is determined to be UREC?
d. How can the testing process be streamlined and less burdensome for small producers faced with UREC or inadvertent drift challenges?

3. Number and Cost of Sampling and Testing:

a. Certifiers: If you could pass along the cost of residue sampling and testing in some circumstances (e.g., complaints, investigations, high-risk operations) and still have this count toward the required 5%, would this change how you approach your sampling program? How?
    i. Would this be valuable to your agency? Why?
    ii. Would this allow you to do more testing?
b. Are there other revisions to cost and the number of samples taken that the Board should consider to strengthen and enhance the effectiveness of sampling in identifying fraud?

Subcommittee Vote:
Motion to accept the discussion document on Residue Testing for a Global Supply Chain: Regulation Review
Motion by: Amy Bruch
Seconded by: Catherine McCluskey
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 2